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December 20, 2004

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20852

RE: Docket Numbers 1995P-0418, 1997P-0197, 1998P-0203, and 2000N-0504 and RIN Number 0910-AC14

Please find enclosed comments pertaining to above subject matter.

2000N-0504

C350

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Pennsylvania's Comments
to FDA Proposal on Egg Safety: Proposed Rule for Prevention of Salmonella Enteritidis in Shell Eggs During Production

Contributors include:

PennAg Industries
Pennsylvania Department of Agriculture
Penn State University
University of Pennsylvania
PEQAP Oversight Committee

December 20, 2004

Pennsylvania's Comments to FDA Proposal on Egg Safety: Proposed Rule for Prevention of Salmonella Enteritidis in Shell Eggs During Production

November 30, 2004

Proposed Requirements and Comments:

1. Are pullet requirements needed, page 47:
   Response: Pullet requirements are needed as part of the program. PEQAP requires environmental (manure swabs) testing of all source pullet houses. If testing is not done, environmental testing is done immediately after placement in destination house.

2. Mandatory Biosecurity, page 47:
   Response: Recommended biosecurity measures are appropriate, and should be implemented for reduction of risk for diseases, including diseases other than SE, but we recommend that any biosecurity recommendations are dictated by the State.

3. Pest control – Flies, page 50, 51 (not currently part of PEQAP):
   Response: We agree that pest control is an important part of reduction of risk of SE in eggs. PEQAP addresses rodent control, but does not currently address fly control. We recommend that fly control be included in the FDA Program but that the State dictates the number of pests allowed for maintaining compliance with the Program.

4. C and D, wet wash all positive houses, page 52:
   Response: We support the requirement for C&D before placement of a new flock if the previous flock environment was SE positive. If details regarding C&D are to be a part of the regulations, we believe the requirement should allow for flexibility in the C&D procedure. We have data that does suggest C&D reduces SE load, but we have additional data that wetting may increase SE in highly soiled areas that were not totally cleaned of organic matter. Overall, if you do not remove all organic matter, the moisture from a wet wash may harbor SE if it is present. Thus the quality of C&D and inspection of the job are important.

   We recommend that if the flock is negative for SE, to allow dry cleaning between flocks, and manure storage in deep pit houses, if necessary, in adverse weather conditions. If the flock is positive for SE, we recommend that the C&D method be determined on a case-by-case basis by the State. Some houses may be allowed to dry clean if they meet certain requirements.

5. Eggs held at 45 degrees F or less if held more than 36 hours, page 56:
   Response: We believe that the 36-hour proposal is realistic (36 hours or less between time of lay and refrigeration). When eggs are refrigerated we recommend that the requirement for this on-farm refrigeration be at a temperature no greater than 55 degrees Fahrenheit provided the eggs are not to be stored on the farm for more than 4 days. The reasons for this are:

   - Eggs are generally held in on-farm coolers for a relatively short period of time.
   - There is evidence that any low level of SE within a naturally infected egg will not undergo significant multiplication until the albumen begins to degrade. Even at room temperature, this may take several weeks.
   - The cost involved in remodeling and operating on-farm coolers to maintain a 45-degree ambient temperature would not show a reasonable cost:benefit ratio.

6. Environmental testing; 40 to 45 weeks only required environmental swab; unless molt, then again 20 weeks post molt, page56:
   Response: We support environmental testing, but recommend adopting PEQAP testing requirements, which require additional environmental testing throughout the life of the flock.

7. If positive swab, must egg test within 24 hours or use lifetime diversion:
   Response: We agree that egg testing should be implemented as soon as possible after an environmental positive test is identified. However, egg testing takes several days at the laboratory, and the laboratories conducting testing may be on strict schedules. Thus it may take several days to fit eggs from a new farm into their testing schedules. Therefore, we recommend that eggs be collected and submitted within 24 hours to the laboratory, and that the laboratory begin testing as soon as possible.

8. Egg testing; 4 tests, every 2 weeks. 1,000 eggs. Page 60:
   Response: PEQAP currently incorporates these guidelines based on science of intermittent shedding of SE.

9. Alternate lifetime egg testing scheme (previously egg positive flocks), page 62:
   Response: We recommend allowing individual states to determine monthly vs. quarterly egg testing for the life of the flock, to be determined by laboratory capacity.

10. Drag swabs, alternate methods, page 64:
    Response: PEQAP requires dragging a swab on each manure row for the entire length of the house. If the manure pits are unsafe for entry, alternative swabbing is allowed. This includes swabbing of walkways, egg belts, manure belts, de-escalators, etc on a case-by-case basis. We recommend adopting the PEQAP protocol.

11. Monthly lifetime egg testing, page 65:
    Response: PEQAP changed to quarterly egg testing to meet FDA recommendations. This protocol seems to be well accepted by program participants and laboratories since implementation in 2004.

12. Testing; comments on conducting/funding (state/fed), page 67:
    Response: We recommend federal funding to state monitoring agencies and testing laboratories.

13. Administrative proposal; one person from farm handles paperwork and oversees compliance:
    Response: PEQAP requires training of participants, but does not require designation of a particular person to maintain records. Is an official (third party) record keeper allowed?

14. Records; must be signed or initialed by on-farm person; Maintain for 1 year. Page 69:
    Response: Would it be possible to submit electronic version of records if signature is required? PEQAP does not require signature.

15. Comment on requirement to turn in written SE prevention plan, to FDA, page 73:
    Response: We do not recommend a written plan for producers. The MOU/Cooperative Agreement and participant program contract will suffice.

16. Comment on requirement to register with FDA, page 74:
    Response: We do not recommend that participants need to register with FDA as long as they are identified within a State agency as part of a program for SE.

17. FDA annual inspections, page 75:
    Response: PEQAP requires twice-yearly inspections. What about facilities out of compliance on inspection? Re-inspection guidelines, etc. Who carries out inspections? Does FDA designate State? Who funds the inspections?
    What about C&D inspections?

18. Enforcement, page 75:

Response: We recommend that this program be enforced in the same way PEQAP is enforced. PDA monitors, compliance board decides on action if non-compliant. Follow FDA guidelines. Alternatively, FDA should enforce. **We do not recommend allowing a local agency to enforce the SE program.**

19. State/local assistance for program, page 87, 88:

i. Inspections
ii. Regulating
iii. Enforcing

Response: We recommend having State or State designee handle these. **We do not recommend having a local agency involved.**

20. Mandatory standards for high risk human populations for comment, page 109:

Response: We suggest that the goal cannot be achieved through mandatory federal requirements at the retail level. We recommend continuing on-farm efforts while continuing educational efforts at retail and consumer levels.

21. 480 eggs for PEQAP outdated, page 183: PEQAP revised MOU (now called a Cooperative Agreement) in 2004. No longer testing 480 eggs; test 1,000 at a time.

22. Laboratory Testing:

Response: These comments are to express concerns about the projected laboratory procedures in the FDA's proposed rule for the egg safety program. The New Bolton Center, Laboratory of Avian Medicine and Pathology opened its Salmonella laboratory in 1989. I have worked in the lab since the first day and have been the head of the unit for 12 of the 15 years. We have processed samples from programs such as the United States Department of Agriculture (USDA) Pilot Project and the Pennsylvania Egg Quality Assurance Program (PEQAP) and have experience in what may be involved with overall laboratory functions needed to complete Salmonella testing. There are four major concerns that I would like to address. These concerns are space requirements and limitations, increases in processing time, required laboratory personnel, and sample increases and costs.

Space requirements

The first laboratory concern is the overall space or critical capacity required. In the current proposed FDA rule, five different agar plates must be stored and used in the testing procedure. To test a single set of 1,000 eggs, we will need a total of 500 agar plates. To test a single set of 12 environmentals, we will need a total of 72 agar plates. This will require a

large space for refrigeration units for storage, as well as many large incubators for the processing of the sample plates. The New Bolton Center PEQAP laboratory has 785 square feet, which is presently filled to capacity in providing all that is needed for the PEQAP procedures. The current PEQAP procedure requires 100 agar plates (compared to 500 in the proposed FDA rule) for a single set of 1,000 eggs and 48 agar plates (compared to 72 in the proposed FDA rule) for a single set of 12 environmentals.

Another factor that will require additional space is the proposed use of the Bismuth Sulfite agar plate. Once this agar plate is made it only has a shelf life of four days and therefore will need to be made frequently. This will require a great deal of countertop space for the pouring and cooling off phases of making these plates, which would take a full day.
We project that existing space would have to be doubled to properly perform the FDA's proposed testing protocol. This additional space would encompass more refrigeration units, more needed incubators and water bath units, countertop space for manufacturing agar plates and racks for incubating eggs at room temperature for four days.

The second issue related to space limitations is the ability to obtain results in a timely manner. Many laboratories, including the PEQAP laboratory at New Bolton Center, will not be able to process large numbers of samples in a timely manner. Currently, we do not have the incubator space to incubate the 500 agar plates needed for a set of eggs or any additional plates from environmental cultures or biochemical agar slants that may require simultaneous incubation at the same temperature.

Manufacturing the Bismuth Sulfite agar plates in the laboratory will divert time and space away from processing samples. It will utilize much of the countertop space needed to crack out egg sets or process environmentals. The four day shelf life will require coordination in timing as to when to start processing samples and when plates have to be made. There will most likely be negative comments from other laboratory personnel about the Bismuth Sulfite agar plate's suitability toward this program goal.

Increase in processing time
Processing and turn around time will increase using the proposed FDA rule. There are several steps in the proposed procedure that are very time consuming. These proposed procedures are most likely better suited to use when testing small numbers of samples or in a research setting. However, due to the large number of samples that are currently required for the PEQAP program and proposed for the FDA program, results will be obtained in a less timely manner. For example, to plate samples that come from eggs using the FDA proposal it will take one technician three and one-half to four hours to plate the samples onto five different selective

agar plates from two different sub-cultures from a single incubated egg pool for a total of 500 plates. The PEQAP program requires direct plating from the 50 incubated egg pools using only two different selective agar plates for a total of 50 minutes for the whole set of eggs compared to almost four hours with the proposed FDA rule.
Below are the basics of what is proposed to perform egg testing under the FDA procedure.

Eggs
Spray with Iodine/alcohol spray

Crack out (20 eggs per pool) and incubate at room temperature for four days

Take out 25 ml of egg and place into 225 ml of Trypicase Soy Broth supplemented with Ferrous Sulfate and let sit for one hour.

Adjust ph to 6.8 with N HCL or 1N NaOH

Incubate for 24 hours at 35 C

Aliquot - 1ml of sample into 10 ml of TT broth (incubate @ 35 C in water bath for 24 hrs),
0.1ml of sample into 10 ml of RV broth (incubate @ 42 C in water bath for 24 hrs)

Streak both set of tubes onto
*Bismuth Sulfite (BS) ** (these plates will need to be made first)*
Brilliant Green with Novobiocin
Brilliant Green
Xylose Lysine Desoxycholate
Xylose Lysine Tergitol 4

Incubate all plates at 35 C for 24 hours. BS plate will need an additional 24 hour incubation.

Biochem suspected colonies onto LIA and TSI.

Serogroup

With the proposed egg procedure it will take a lab technician about 17 hours of the workweek to perform the steps to test a single set of 1,000 eggs. To test a set of 1,000 eggs using the PEQAP procedure it takes about five and one-half hours of a technician's workweek.

Below are the basics of what is proposed to perform environmental testing under the FDA procedure.

Environmentals

Add 100 ml of buffer peptone water to each environmental sample.

Incubate @ 35 C for 24 hours

Aliquot - 1ml of sample into 10 ml of TT broth (incubate @ 42 C in water bath for 24 hrs),
0.1ml of sample into 10 ml of RV broth (incubate @ 42 C in water bath for 24 hrs)

Streak both set of tubes onto
Bismuth Sulfite (these plates will need to be made first)
Brilliant Green with Novobiocin
Xylose Lysine Tergitol 4

Incubate all plates at 35 C for 24 hours. BS plate will need an additional 24 hour incubation.

Pick at least five colonies from each of the three plates and for each broth. (This could add up to 360 isolations for a single set of environmentals that contained just 12 samples)

Biochem suspected colonies onto LIA and TSI.

Serogroup

With the proposed environmental procedure it will take a lab technician about 10 ½ hours of the workweek to perform the steps to test a single set of 12 Salmonella positive environmentals. One of the most time consuming steps is the number of isolations it is required to pick per agar plate. To test a single set of 12 Salmonella positive environmentals using the PEQAP procedure takes about four hours of a technician's workweek.

With the submission of several sets of 1,000 eggs and many sets of environmentals per week the time needed to process samples will greatly affect the turn around time on all samples.

Laboratory personnel
The laboratories must have adequate personnel to handle the increased workload resulting from the new proposal. Processing environmentals under the FDA proposed procedure will take two and one-half times longer than the current PEQAP method. Processing eggs will take three

times longer than the PEQAP method. In addition to the increased time per sample, the FDA proposed rule will require an increase in the number of eggs tested compared with the current PEQAP procedure. This increase is based upon having to test four sets of 1,000 eggs for each Salmonella positive set of environmental samples (at 45 weeks of age and at post molt) as well as the monthly testing of 1,000 eggs for each flock found to contain Salmonella in any of their egg testings. Currently, the PEQAP laboratory at New Bolton Center employs one full time technician and one part-time technician to complete the workload. Using the estimated time increases for the proposed procedure the laboratory will need to add two full time technicians. This is assuming that adequate space is made available.

Cost increases

Lastly, there is concern about costs to perform these tests. There will be a significant start-up cost involved with adding space and new incubators. Each incubator will cost approximately $5,000 and two would be needed to hold all the agar plates used for the sampling of eggs and environmentals. There will also be the need for three additional refrigeration units at a cost of approximately $800 each to store all the supplies and the need to purchase two water bath units for incubation of sample tubes for eggs and environmentals. In addition to the extra space and equipment, supply costs will increase because of the five different agar plates and numerous biochemical agar slants required, increased isolations requiring group D antiserum, and many other items mentioned in the proposed procedure.

We have calculated that a single positive environmental could cost as much as $55 for supplies alone. A set of environmentals with 12 samples could cost as much $660 to perform. The two biggest cost factors include the biochemical agar tests and antiserum needed to test the 30 isolations required per individual sample. The PEQAP cost to run a single positive environmental sample is only $10, or $120 for a set of 12. The cost to process egg sets will also increase. We have calculated that an individual positive egg pool, consisting of 20 eggs, will cost approximately $63. Again the number of plates used to perform the test, as well as all the isolations picked, will greatly increase the number of biochemical agar slants and group D antiserum needed. The cost of a single positive egg pool under the PEQAP program costs about $14.

Summary

The proposed FDA protocol raises many concerns that will result in an increase in turn around time to process samples. Costs, space, and labor requirements will obstruct many laboratories from being able to participate in this program. This in turn may increase workloads for the laboratories already participating, putting the overall objective of this

program in jeopardy. To address these issues, alternative laboratory protocols must be considered and evaluated to better meet the needs of high volume testing programs such as this one.

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Questions for Scientific Experts in SE

1. In your opinion, can the existing laboratory system handle the volume of SE tests contemplated in FDA's rule? Will these same labs be conducting LPAI testing under the new national program, or will the two tests involve different labs? FDA has provided for a 1-year implementation period after the rule is published for producers with 50,000 or more hens. It could be anticipated that they may assert that this provides ample time for laboratories to increase their capacity. Is that a reasonable expectation?

   a. No – Sometimes in PA we can barley handle PEQAP samples (with other demands on the 3 lab system) and we've had 10 years to get up to speed.

   b. Don't know about vision for dual labs or separate labs for SE & LPAI?

   c. I do not believe 1 year is ample for producers to get up to speed OR labs to get up to speed. Furthermore, this will require additional money that I don't believe FDA has.

2. Do know of any data on the frequency of environmental positives and how often egg tests are positive?

   Today in the PEQAP environmental positives are less than 10% and the number of samples that are positive is approx. 1%. This is considerably reduced from 1992 when 38% of houses were SE pos and 26% of samples were positive.

3. In your judgment, would it be appropriate for FDA to adopt a "recognition regime," whereby the agency would recognize certain existing QA plans (e.g., PEQAP, UEP's 5-Star Program) as meeting its requirements for on-farm measures, so that if a producer was in compliance with these programs (and was carrying out all required testing), he or she would be in compliance with FDA's rule? Would these programs need to be modified if the industry were to propose them as serving to demonstrate compliance with FDA's rule?

   a. Yes for PEQAP and other equivalent programs – What about post-harvest HACCP parts of PEQAP eg. Washing, refrigeration, and pH requirements?

   b. Some would need to be modified e.g. some test at different ages (end of lay) and others have no post-harvest HACCP.

   c. However, some regions of the country may have different SE challenges that require site specific CCP's not like PEQAP or CEQAP.

   d. One size does not fit all.

4. Would breakers need to take any additional steps to ensure the safety of eggs from houses with positive egg tests? Would the existing requirement for a 5-log reduction be sufficient to render the product safe?

   Yes, I feel a pre-harvest program is still required of breakers or those in shell pasteurizing. You still need good SE reduction procedures and not just band aide procedures at the end.

5. What is your opinion of the requirement that eggs held more than 36 hours be refrigerated? What would be the impact of permitting a variance from this requirement for breakers with dedicated production where eggs need to be held over a weekend or holiday? In your judgment, is the greater risk to public health (a) the risk from not refrigerating eggs held more than 36 hours at an off-line operation, or (b) the risk from a more drastic temperature change when those same eggs are first refrigerated, then washed?

   I think all eggs should be refrigerated after gathering. The faster you cool the better the egg quality and safety. Breakers need the same requirement because we should always be trying to reduce SE levels. They must use graded eggs for breaking too. So quality and safety means the same for breakers. It is not an issue in my mind to gather on weekends and refrigerate. If they are leaving eggs in the hen house on weekends and holidays because the breaker equipment does not run at these times this is a great risk factor! Hot hen houses, greater number eggs in the belts and cracks, leakers and lost eggs. More exposure to flies and rodents and air contamination with SE. Not valid cost argument either. Greater egg losses outweigh cost of cooler and off line loading over time.

6. How do you assess FDA's somewhat tentative comments about vaccination as an SE control measure? Are FDA's estimates of vaccination cost accurate? In your opinion, would it be appropriate to require vaccination? To provide positive incentives for vaccine use? What would be the pros and cons of permitting an environmental test closer to depopulation than 40-45 weeks, available only for vaccinated flocks?

   Vaccination is an important tool that can help deal with a reoccurring SE challenge. I am not versed in the costs and can not comment. I believe it is not a good idea to REQUIRE vaccination; it should only be used when necessary. Eg. "A tool in the tool box." Incentives would be nice; they may encourage those to do it that might not otherwise feel obligated. Environmental testing at depopulation is a waste of time e.g. eggs already marketed if SE positive. Testing before 40-45wks begins egg testing in time to do some good and also motivates C&D after the flock finished.

7. Given trends in recent years, do you feel the public health danger posed by SE justifies a regulation of the scope which FDA has proposed? What is your overall view of FDA's proposal?

   I'm not sure, only testing will verify the need. I believe FDA needs to justify in states or companies not conducting PEQAP like procedures it is warranted. E.g. SE may not be an issue in some regions of the US like desert SW?? FDA must justify National Program in my mind. Besides the trend is in regions that were a problem like PA and the NE the situation is better and still improving.

8. Do you agree with the exclusion of producers with fewer than 3,000 birds from the proposed rule? How would you compare the risks from eggs produced at these operations with the risks from eggs produced at larger farms?

   I agree with the exclusion, but feel all eggs should be and can easily be refrigerated after gathering. The 36 hour release from refrigeration is not necessary and important from and egg safety and quality standpoint.

9. From the standpoint of SE control, how would you assess the pros and cons of FDA contracting with the Agricultural Marketing Service and/or state agencies to carry out inspections and ensure compliance – e.g., through additional procedures at the time of quarterly inspections under the existing Shell Egg Surveillance Program?

   Some states are capable of handling this, but others have neither the staff nor the laboratory services. Those egg producers may need to come to other state programs to get the job done, or acceptable industry based programs if 5- Star or others can be authorized

10. What is your view of the current science on SE and induced molting?

    New forced molting techniques with no feed withdrawal are an unknown regarding SE shedding by hens. While conventional molts procedures appeared to increase SE shedding, new techniques are have not been researched to my knowledge.

11. What other scientific or technical issues do you believe UEP should consider?

    I am concerned about training and who will do it? We have PEQAP training and certification of our participants. CA does as well. Can we continue to train and certify in our states and how much rework will be required with the "FDA Model" Will we be consulted or part of the FDA certification training teams?

Submitted by: Dr. Paul Patterson, Penn State University
Assoc. Professor of Poultry Science

Comments to FDA 21 CFR Parts 16 and 118 (Prevention of Salmonella Enteritidis in Shell Eggs During Production) Proposed Rule

p. 56835 Last paragraph referencing No. 46 Davison et al. 1997.
Original reference to Rodent Indexing (RI) and the development of method for quantification mice numbers on commercial poultry farms is: Henzler, David J., "Determining the number of mice on farms is difficult task," Poultry Times, VOL. XL NO. 6 March 15, 1993. This is later referenced in Seal Rodents and S. enteritidis out of your poultry houses, Pennsylvania Farmer, October 1993. Also early references include: Guidelines on Detection and Monitoring of Salmonella Infected Poultry Flocks with Particular Reference to Salmonella Enteritidis, ZOON/94.173 and Guidelines on Cleaning, Disinfection and Vector Control in Salmonella Infected Poultry Flocks, WHO/ZOON 94.172. An additional reference is: Guard-Petter, J., Henzler, D.J., Rahman, M., and Carlson, R.W., "On-farm monitoring of mouse-invasive Salmonella enterica serovar Enteritidis and a model for its association with the production of contaminated eggs. Appl. Environ. Microbiol. 63:1588-1593, 1997. A later detailed description of the methodology of Rodent Indexing noted in the above references is found in your reference No. 48 Henzler, D. J. and H. M. Opitz. Pgs 337 and 338, 1999.

General comments in the proposal is to require record keeping for environmental and egg sampling collections, refrigeration temperatures, egg treatment processes which significantly lower the risk of any S. enteritidis contamination is important as is the absolute need to maintain records of both rodent control methods and Rodent Index Monitoring. A minimal program for both recording rodent numbers and rodent control practices are detailed below.

An acceptable rating is given if the Rodent Control Logbook is up-to-date with minimum of monthly entries. The entries must include dates of bait applications, types of bait used, Rodent Indexes standardized to a weekly count, dates of Tin Cat servicing, and initials or signatures of individuals responsible for tasks. A minimum of one Rodent Index (e.g. any 7-day evaluation period) must be done and recorded each month. This log must be maintained on the premises. Comments noting specific rodent activity at locations within certain areas of the poultry house (including a particular bait stations or Tin Cats) are encouraged.

An unacceptable rating is given if a RI of 2 was determined for two or more RI evaluations (e.g. two 7-day evaluation period) or a RI of 3 (e.g. any 7-day evaluation period) between any evaluation rating periods (approximately every 6 months). Determination of Rodent Index (RI): Record the number of mice captured each week in 12 Tin Cat traps and convert these numbers to a Rodent Index (RI). The most effective Rodent Indexing requires placing0.5 ounce of chicken feed in the traps with the traps set in the areas most likely to catch mice (that is, along cage walkways and against walls). The traps, which remain in the poultry house for 7 days, are checked twice within the 7 days, and any trap that did not catch a mouse at the first check is moved a minimum of 15 feet. Traps that caught a mouse are placed back in the same location. At the end of 7

days, the traps are checked a second time. The captured mice are killed, and the total count of mice captured in the 7 days is recorded. The following formula is used to assign RI:

$$RI = \frac{(\text{number of mice caught in all traps} / \text{number of functioning traps}) \times 12}{\text{number of day's traps are set}} \times 7$$

This formula adjusts for periods of time traps are set which are longer or shorter than 7 days and where more than 12 traps may have been used, and standardizes all mouse catches to a one week period using 12Tin Cat traps. The RI's are grouped as follows: 0-10 mice = 1 (low density), 11-25 mice = 2 (moderate density), and 26 or more mice = 3 (high density). A Rodent Index will be done by an outside reviewer; generally either a trained State or Federal employee if the inspection indicates the RI's recorded may not be accurate. Reasons may include improper protocol by the producer, lack of appropriate functioning Tin Cat traps, unacceptable external rodent entry sites or internal rodent harborage areas.

General comments regarding training and whom and what constitutes a "certified individual" to monitor *S. enteritidis* reduction methods on farm follow. The most appropriate individuals to monitor practices/procedures/methods employed on participating farms for the proposed FDA SE Shell Egg regulations are third-party individuals trained and employed by state or federal Governments. When appropriately trained and experienced- these persons provide the most objective evaluations and when needed most reliable sample collection.

The suggestion that each farm maintain an individual responsible for SE risk reduction practices is important. Without "local" understanding and ownership of accepted methods and standards required for the control and reduction of *S. enteritidis* on farm these same practices are frequently only partially applied. Training programs including previously attended instruction and workshops offered by state, federal, and/or university personnel ideally in combination with poultry industry representatives are the best. Allowing some latitude for the acceptance of multimedia preparations (CD's, video, other) will expand capabilities for training opportunities. "Recertification or training" will be needed as farm employees' change and new science dictate the need for appropriate revisions.

Pgs. 56837, 56838 Last line of p. 56837 and first paragraph p. 56838 Ref. No. 58, refers to an individual from the PEQAP program stated that 75 percent of environmental positives will be caught with one environmental test was likely David J. Henzler. This reference comes from a comprehensive review of available Salmonella enteritidis and SE Pilot Project date extending from origin of SE Pilot Project (April 12, 1992) to and including an analysis of five years and two months worth of Pennsylvania Egg Quality Assurance Program (PEQAP) data on 1,107 commercial layer flocks. The specific reference is: Henzler, D.J., Henninger, M., and P. Debok, "A Five Year (1994 – 1999) Critical Analysis of the Pennsylvania Egg

Quality Assurance Program (PEQAP)," @ 136th Annual Convention of the American Veterinary Medical Association/American Association of Avian Pathologist, New Orleans, Louisianan, July 10-14, 1999. Poultry Poster No. 45, Convention program, p. 98.

These data demonstrate Figs. 1-3, that combined analysis found of three environmental tests taken from 1,107 flocks with 154 *S. enteritidis* positive flocks found that 83 (75.5%) and 18 (40.9%) on multiple house complexes and single stand alone houses had their 30 week environmental test positive. Hence, the 30 week test which is the first evaluation of flocks in PEQAP post pullet housing and near or at the time of peak production would be the most important environmental testing to categorize a flock based on *S. enteritidis* environmental status. Unpublished data by Henzler et al. from January 1999 through June 2002 on a subset of Pennsylvania layers would identify a late environmental sampling (manure drag swabs) as the single most likely test to identify a flock as *S. enteritidis* positive given earlier tests at 30, 45 and 7 weeks post molt evaluation. This late flock evaluation (4- 8 weeks prior to spent hen removal) among other variables allows for the aging process of commercial hens in combination with SE risk reduction factors to have their full impact in the ecology of *S. enteritidis* in commercial layer hens. The later test would best categorize a flock as *S. enteritidis* positive of all tests but producers might miss the opportunity for further layer house intervention practices including those for replacement pullets such as *S. enteritidis* vaccination. In addition, by not identifying a portion of these flocks which become *S. enteritidis* positive early in the laying cycle, the potential for the production of *S. enteritidis* positive eggs and the public health consequences thereof must be assessed.

Comments from:

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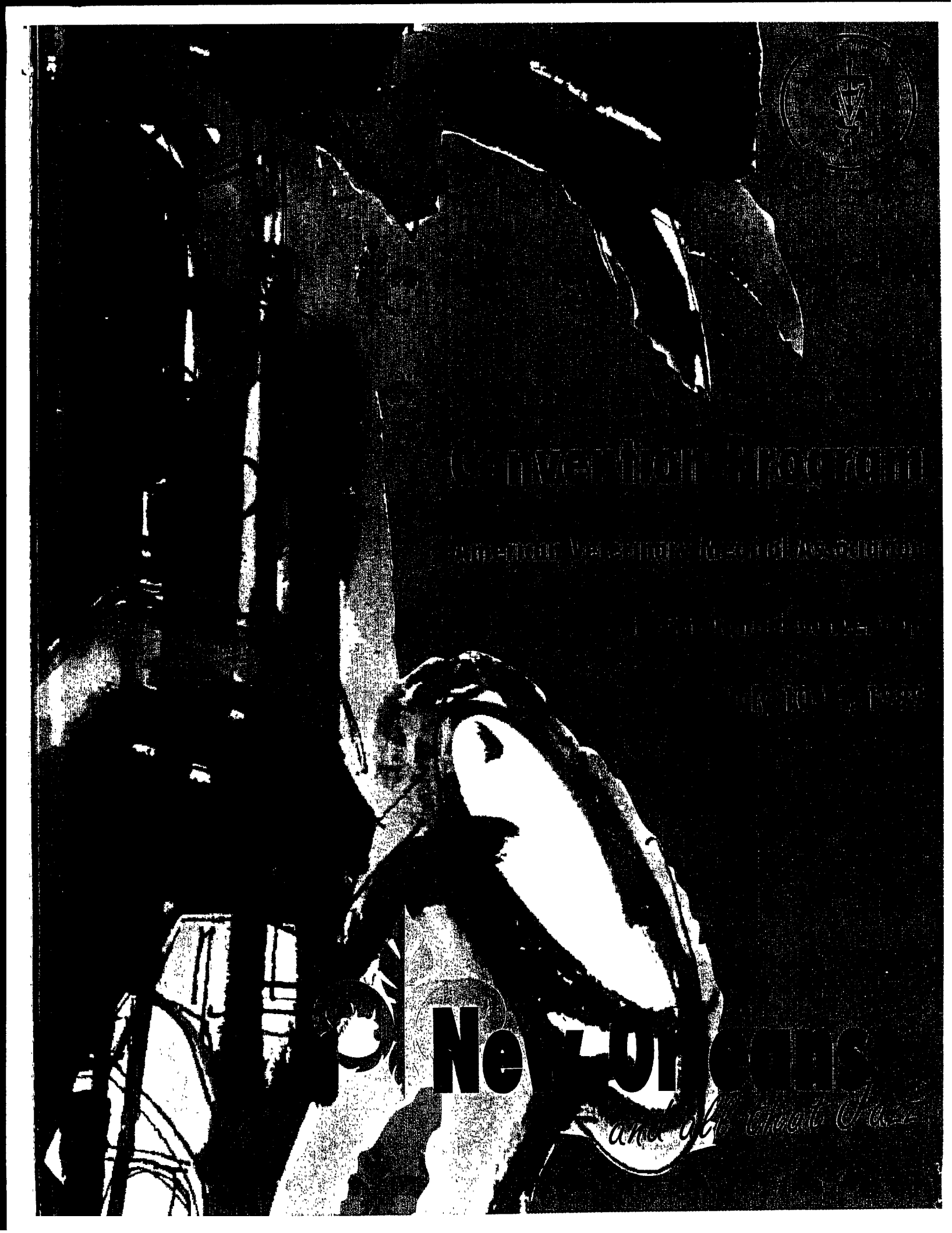
October 26, 2004

re: Some selected references attached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and

Program

136th AVMA Annual Convention

July 10–14, 1999

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REGISTRATION HOURS

Ernest N. Morial Convention Center

Friday, July 9....8 am – 8 pm
Saturday, July 10....7 am – 5 pm
Sunday, July 11....8 am – 5 pm
Monday, July 12....8 am – 5 pm
Tuesday, July 13....8 am – 5 pm
Wednesday, July 14....8 am – 12 pm

OFFICES

Ernest N. Morial Convention Center

Information Desk
Hall A Lobby....670-4815
Press Room
Room 216....670-4801
Convention News Office
Room 223....670-4806
Audiovisual Center
Rooms 214....670-4818
Speaker Information/Speaker Ready Room
Rooms 215....670-4819
Tour Desk
Welcome Center—Hall A Lobby....670-4820

New Orleans Marriott

AVMA Business Office
Bonaparte....553-5650

Hours
Tuesday, July 6....8 am – 5 pm
Wednesday, July 7 through Tuesday, July 13....7 am – 5 pm
Wednesday, July 14....7 am – 2 pm

Auxiliary Office
Galvez....581-1000

Audiovisual Center
Iberville....553-5653

Advance Registration
Regent
Wednesday, July 7....8 am – 5 pm
Thursday, July 8....8 am – 1 pm

Information published is current as of June 15, 1999. Updated information will be published in the Saturday edition of the convention newspaper.

Poultry Poster Presentations

Ernest N. Morial Convention Center
Room RO1 (Tentative)

Sunday, July 11—8:00 am to 4:45 pm
Monday, July 12—8:00 am to 4:45 pm
Tuesday, July 13—8:00 am to 4:45pm
Wednesday, July 14—8:00 am to 11:15 am

PP 1 The Fate of Infectious Bursal Disease Virus in Specific-pathogen Layer Chicks and in Maternally Immune Broiler Chicks Following Vaccination at 1 Day of Age
H. Knoblich, S. Sommer, and D. Jackwoood

PP 2 Effect of Virulent Strain of Infectious Bursal Disease Virus (IBVD) on the Pathogenicity of *Cryptosporidium bileyi* and the Development of Acquired Immunity to the Parasite
H. Abrassi, F. Coudert, Y. Cherel, J. Brugere-Picoux, and M. Naciri

PP 3 Use of a Chicken Anemia Virus Antibody Test for Monitoring Protective Antibody Titers
V. Leathers

PP 4 Using Expressed SI Gene Protein as an Antigen for the Detection of Antibody Against Infectious Bronchitis Virus by ELISA
C-H. Wang

PP 5 Genetic Shift and Drift Observed in Avian Infectious Bronchitis Virus Strain DE072
C-W. Lee and M. Jackwood

PP 6 1998 Respiratory Outbreak in Mississippi Broilers
R. Montgomery, F. Austin, C. Wang, and C. Boyle

PP 7 Rapid Characterization of Infectious Laryngotracheitis Virus by Restriction Fragment Polymorphism of PCR Products
M. Garica, S. Riblet, J. Humbert, and J. Linares

PP 8 Development and Characterization of Monoclonal Antibodies to Avian Leukosis Virus Subgroup-J
A. Qin, L. Lee, and P. Wu

PP9 Withdrawn

PP 10 Correlation of Thyroid Lesions and Function with Performance in Broilers Naturally Infected with Avian Leukosis Virus Subgroup-J
T. Brown, N. Stedman, S. Gharaibeh, Y-B. Kim, and M. Pantin-Vera

PP 11 A Survey of Incidence of ALV-J Infection in Broiler Breeders and its Effect on Breeder and Broiler Performance
J. Gidlewski and K. Opengart

PP 12 Simplified Nested-PCR for Detection of Avian Leukosis Virus Subgroup-J
S. Riblet, H. Moscoso, and M. Garcia

PP 13 Immunotherapeutic Approaches to Avian Leukosis Virus
B. Singbeil, T. Girshick, A. Avakian, A. Harrison, and D. Grosse

PP 14 Construction of Recombinant Marek's Disease Virus Type 2 Expressing the S1 Glycoprotein of Infectious Bronchitis Virus Using a Green Fluorescent Protein Expression Cassette
C-S. Song, Y-J. Lee, H-K. Jang, and T. Mikami

PP 15 Development of M Gene Based PCR for the Detection and Differentiation of Avian Pneumovirus Isolates from Turkeys
H-J. Shin, G. Rajashekara, K. Nagaraja, D. Halvorson, and S. Goyal

PP 16 Characterization of Avian Pneumovirus
D. Halvorson, E. Townsend, D. Shaw, and K. Nagaraja

PP 17 Molecular Characterization of the Fusion and Matrix Proteins (M and M2) Genes of a Newly Emerging Avian Pneumovirus
D. Arshud, K. Tune, S. Goyal, and V. Kapur

PP 18 Antigen Trafficking and Immune Alterations Induced by Small Round Virus Associated with Poult Enteritis and Mortality Syndrome of Turkeys
M. Qureshi, Y. Saif, and M. Yu

PP 19 Studies on the Pathophysiology of Enteric Viral Infection in the Turkey Embryo Model
A. Ali, and D. Reynolds

PP 20 Virulence of Pigeon Paramyxovirus-1 Isolates for Domestic Chickens
G. Kommers, C. Brown, B. Seal, and D. King

PP 21 Detection of Muscovy Duck Parvovirus Infection in Ducks in Pennsylvania
D. Senne, J. Pedersen, A. Nesselrodt, and B. Panigrahy

PP 22 Identification and Characterization of Muscovy Duck Parvovirus Isolated from a Commercial Flock of Muscovy Ducks
P. Wollcock, V. Jestin, and H. Shivaprasad,

PP 23 Immune Cell Tropism and Tissue Distribution of Duck Virus Enteritis
S. Shawky

PP 24 Presence of Marek's Disease Virus in Quail Fibroblast Cell Lines
T. Yamaguchi

PP 25 Identification of Hot-spo[redacted]d Quantification of Salmonella and Fecal Coliforms as a Function of Environmental Parameters in Poultry Houses
C Eriksson de Rezende, E Mallinson, R. Morales and S. Joseph

PP 26 Role of Fimbrial Genes in the Pathogenesis of *Salmonella enteritidis*
K. Nagaraia, G. Rajashekara, S. Munir, D. Halvorson, and C. Wells

PP 27 Identification of the Immunophilins Involved in Intracellular Survival of the Avian Pathogen, *Salmonella typhimurium* var Copenhagen
S. Horne, M. Breider, C. Giddings, L. Nolan, and K. Young

PP 28 Survival and Destruction of *E coli* O157:H7 and *S typhimurium* in Poultry and Cattle Manure
S. Himathongkham, H. Riemann, and S. Bahari

PP 29 Ongoing Examination of Avian *Escherichia coli* Isolates for Iss Sequences
L. Nolan, J. Ebert, S. Horne, and S. Foley

PP 30 Characterization of Multiple Flouroquinolone Resistance Among Pathogenic Avian *Escherichia coli* Isolates
D. White, L. Piddock, and J. Maurer

PP 31 Isolation, Identification and Protection Obtained of Adenovirus Against IBH
M. Vasquez, C. Gonzalez, R. Reya, and G. Torres

PP 32 Pathogenic and Molecular Characterization of *Mycoplasma sturni*
D. Ley and S. Geary

PP 33 Susceptibility of Avian Mycoplasmas to Antibiotics Commonly Used in Poultry
C. Wang and M. Ewing

PP 34 Cross Reacting Effect of *Mycoplasma synoviae* Antigen on Sera from Chickens Artificially Infected with *H gallisepticum*
E. Nascimento, G. Mendonca, S. Dias, G. Lignon, M. Nascimento, O. Deusdara, and J. Ito

PP 35 The Molecular Characterization of Erythromycin Resistant Avian *Staphylococcus* sp and its Comparison with Human Isolates
H. Ghori and M. Nawaz

PP 36 Use of Sodium Bisulphate Litter Additive to Suppress *Campylobacter* Colonization in Broilers
S. Shane, J. Fleniken, and M. Terich

PP 37 Use of Outer Membrane Proteins for Serological Detection of *Ornithobacterium rhinotracheale* Infection in Turkeys
V. Lopes, K. Nagaraja, A. Back, G. Rajashekara, and D. Halvorson

PP 38 Investigatio[redacted] Bacterial Resistance to Commercial Dis[redacted]ctants Using a Novel Technique
J. Sander and C. Hofacre

PP 39 Presence of Fluoroquinolone Resistant Bacteria in Poultry Litter
C. Hofacre, A. Rene' de Cotret, A. Garritty, S. Thayer, and J. Maurer

PP 40 Safety of Aureomycin (chlortetracycline) Granular Premix for Egg-laying Chickens
S. Clark, T. Cheng, and A. Venne

PP 41 Characterization of the Pacheco's Disease Virus Genome
C. Keeler, Jr. and D. Thur

PP 42 Serosurvey of Avian Pathogens in Ratites
E. Ley, T. Morishita, R. Mohan, and B. Harr

PP 43 Renal Cryptosporidiosis in Commercial Laying Hens
D. Trampel and T. Pepper

PP 44 Disseminated Granulomatous Lesions in Turkeys: A Case Report
F. Clark, J. Beasley, and J. Skeeles

PP 45 A Four Year (1994-1998) Critical Analysis of the Pennsylvania Egg Quality Assurance Program
D. Henzler, M. Henninger, D. Kradel, and P. DeBok

PP 46 Coronary Artery Aneurysm in Male Commercial Turkeys
H. Shivaprasad and R. Crespo

PP 47 Use of Ultrasonography to Assess Development of Enlarged Sternal Bursa in Turkeys
F. Jirjis, P. Watter, S. Noll, D. Shaw, and D. Halvorson

PP 48 The Poultry Health Management Group at North Carolina State University: Redefining the Learning Environment
J-P. Vaillancourt, H. Barnes, D. Ley, and D. Wages

PP 49 Immunomodulation of Chicken Splenocytes Determined by Flow Cytometry Analysis
L. Garcia-Camacho and D. Bounous

PP 50 Detection of Natural and Recombinant Chicken Interferon-Gamma
J. Elyar, C. Romero, and K. Evans

PP 51 Prevalence of *Cryptosporidium* spp Among Ostriches in Jordan
M. Abo-Shehada and F. Qammash